IN THE UNITED STATED DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

United States of America,
Plaintiff

v.

Lao Trading Company and
Peng Bandith,
Defendants.

No: 3:10-cv-00928

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned counsel, having filed a Complaint for Permanent Injunction against Lao Trading Company and its owner, Mr. Peng Bandith (collectively, "Defendants"), and Defendants having appeared and consented to entry of this decree without contest and before any testimony has been taken, and the United States of America, having consented to this decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and personal jurisdiction over all the parties to this action pursuant to 28 U.S.C. § 1345 and the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*

2. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) of the Act by adulterating, or causing the adulteration of, articles of food within the

meaning of 21 U.S.C. § 321(f). The Complaint alleges that the articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or been rendered injurious to health.

3. Upon entry of this decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors and assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from doing or causing to be done, directly or indirectly, any act that violates 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342, while held for sale after shipment in interstate commerce.

4. Upon entry of this decree, Defendants shall establish and implement a written sanitation control program for every facility where Defendants hold articles of food for delivery for introduction into interstate commerce, and all food handling and storage equipment therein. The written sanitation control program or programs shall be designed to ensure that the subject facilities and all equipment therein are maintained continuously in a sanitary condition to prevent conditions under which food may become contaminated with filth. Defendants shall assign

responsibility and authority for the implementation of the written sanitation control program or programs to a person or persons who, by reason of education, training, and experience in sanitation work, is competent and authorized to maintain the subject facilities and all equipment therein in a sanitary condition.

5. Within thirty calendar days of the entry of this decree, Defendants shall submit to the United States Food and Drug Administration ("FDA") the written sanitation control program or programs described in paragraph 4 and the name(s) and qualifications of the person(s) assigned authority and responsibility for continuously implementing the program or programs.

6. Within six months of the entry of this decree and once every twelve months thereafter, the person or persons assigned authority for implementing the written sanitation control program(s) described in paragraph 4 shall provide FDA with a declaration pursuant to 28 U.S.C. § 1746 describing the status of Defendants' sanitation control efforts and certifying that Defendants have implemented the FDA-approved sanitation control program.

7. Upon entry of this decree, Defendants shall retain an independent person or persons (the "Auditor") to conduct audit inspections of Defendants' facilities not less than once every six months for a period of one year and not less than once every twelve months for a period of two years thereafter, for a total of three years of auditing. The Auditor shall be qualified by education, training, and

experience to conduct such inspections, and shall be without personal or financial ties to any Defendant or any officer, director, or employee of any Defendant or their immediate families. Defendants shall notify FDA in writing of the identity of the Auditor and provide FDA with information in writing regarding the Auditor's qualifications, background, education, training, and experience as soon as such Auditor is retained.

A. The audit shall evaluate whether Defendants are maintaining their facilities in compliance with the requirements of 21 U.S.C. § 342(a)(4), including, but not limited to, whether: (i) there is evidence of rodents, birds, or other pests contaminating the food storage areas; (ii) whether Defendants have adequately closed entryways for rodents, birds, and/or other pests; (iii) whether food is stored at proper temperatures; (iv) whether food is stored an appropriate distance from the floor and walls to minimize infestations by rodents, birds, and/or other pests; and (v) whether there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations.

B. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") identifying in detail any deviations from the requirements of 21 U.S.C. § 342(a)(4) ("Audit Report Observations"). As part of every Audit Report, except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to

correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten calendar days after the date each audit inspection is completed. If an Audit Report contains any Audit Report Observations FDA deems significant, FDA may, in its discretion, require that the three-year auditing cycle begin anew. In addition, Defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at the their facilities and shall make the Audit Reports and underlying data available to FDA upon request.

C. If an Audit Report contains any Audit Report Observations, Defendants shall, within ten calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of an Audit Report Observation will take longer than ten calendar days, Defendants shall, within seven calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification describing why the additional time is necessary. Any such Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty calendar days of Defendants' receipt of an Audit Report,

or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within ten calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected.

8. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, articles of food, containers, and packaging material(s) therein; to take photographs and make video recordings; to take samples of Defendants' articles of food, containers, and packaging material(s); to examine and copy all records relating to the receiving, processing, preparing, packing, holding, and distributing of any and all articles of food, and to the sanitation of the facility. The inspections shall be permitted upon presenting a copy of this decree and appropriate credentials. The inspection authority granted by this decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. If, at any time after this decree has been entered, FDA determines that Defendants have failed to comply with any provision of this decree, or has violated

the Act or any applicable regulations at their facilities, or that additional actions are necessary to achieve compliance with this decree, the Act, or any applicable regulations, FDA may, as and when it deems necessary, order Defendants immediately to take one of the following actions:

A. cease receiving, manufacturing, preparing, packing, labeling, holding, or distributing articles of food until Defendants receive written notification from FDA that they appear to be in compliance with this decree, the Act, and its implementing regulations, and that they may resume operations;

B. recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, customers, or consumers;

C. submit samples of articles of food to a qualified laboratory to determine whether it is contaminated with chemicals, toxins, microorganisms, or filth;

D. take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this decree, and the Act, or its implementing regulations, including but not limited to requiring that Defendants re-implement or re-institute any of the requirements of this decree.

10. If, at any time after entry of this decree, FDA notifies Defendants in writing that conditions in their facilities render articles of food held therein adulterated within the meaning of 21 U.S.C. § 342(a)(4) based on the results of an

inspection, Audit Report, or other information, and directs Defendants to discontinue receiving, introducing, delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce articles of food at or from their facilities, Defendants shall comply with such order unless and until:

A. An FDA representative inspects Defendants' facilities as he or she deems necessary in order to determine whether the facilities, articles of food, and sanitation control program(s) are in compliance with the Act, applicable regulations, and the requirements of this decree. The cost of all such inspections will be borne by Defendants at the rates specified in paragraph 11 below;

B. Defendants provide the FDA representative access to all records of the receipt, storage, and shipment of articles of food as such representative deems necessary; and

C. The FDA representative notifies Defendants in writing that Defendants appear to be in compliance with the Act, applicable regulations, and the requirements of this decree.

11. Defendants shall reimburse the United States for the costs of supervising Defendants' compliance with the terms of this decree, including all costs associated with any inspections, examinations, reviews, evaluations, or analyses conducted pursuant to this decree, at the standard rates prevailing at the

time the activities are accomplished. As of the date this decree is signed by the parties, the rates are $87.57 per hour or fraction thereof per representative for time spent on supervision other than laboratory and analytical work; $104.96 per hour or fraction thereof per representative for laboratory and analytical work; and 50 cents per mile for travel expenses. In the event that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this court.

12. Defendants shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a Court of any FDA decision rendered pursuant to this decree shall be conducted without any discovery and shall be based exclusively upon the written record that was before FDA at the time of the decision.

13. Should the United States bring, and prevail in, a contempt action to enforce the terms of this decree, Defendants agree to pay all attorney's fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

14. Defendants shall notify FDA, at the address specified in paragraph 17 below, at least ten business days before any of the following events occur or within

ten calendar days after learning that any of the following events will occur if the event would affect Defendants' compliance obligations arising out of this decree: any reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the legal status of Lao Trading Company.

15. Defendants shall hold a general meeting or series of smaller meetings for all persons with responsibility for operation, maintenance, cleaning, and/or pest control at any facility where Defendants hold articles of food after shipment in interstate commerce or for delivery for introduction into interstate commerce within twenty calendar days of the entry of this decree, and upon the opening of any new such facility, at which it shall describe the terms and obligations of this decree.

16. Defendants shall post a copy of this decree on a bulletin board in the employee common area of any facility where Defendants hold articles of food after shipment in interstate commerce or for delivery for introduction into interstate commerce within ten calendar days of the entry of this decree or, if any new such facility is opened, within ten calendar days of opening, and shall ensure that the decree remains posted for a period of at least six months.

17. All notifications, correspondence, and communications to FDA required by the terms of this decree shall be addressed to:

District Director
New Orleans District Office
U.S. Food and Drug Administration
Department of Health and Human Services
404 BNA Drive, Suite 500
Nashville, TN 37217

and to

Jerrry E. Martin
United States Attorney
(Attention: Assistant U.S. Attorney S. Delk Kennedy)
110 Ninth Avenue, South
Suite A961
Nashville, TN 37203-3870

18. This court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED:

Dated this 13th day of October, 2010.

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

Lao Trading Company
Defendant

Owner Peng Bandith
Defendant

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